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PATENT SPECIFICATION

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(21) Application No. 42509/73 (22) Filed 10 Sept. 1973
(61) Patent of Addition to No. 1419962 dated 20 Dec. 1972
(44) Complete Specification published 22 Sept. 1976
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(19)

(54) ABSORBENT POLYURETHANE FOAMS AND THEIR APPLICATION AS SURGICAL DRESSINGS

(71) I, PETER MAURICE LOCK, a British Subject, of "Petrosa", 53B Maidstone Road, Rainham, Gillingham, Kent, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

sterile state under sterile conditions to prevent harmful bacteria breeding close to or in the wound; this material does not absorb exudate satisfactorily, thus causing pooling in the wound which is not desirable.

Processes for subjection of polyurethane foams to heat and pressure are well known in the prior art. It is to be understood that the present invention does not claim as novel such processes in general, but rather provides a disclosure enabling certain polyurethane foams to be rendered absorbent by application of a heat/pressure treatment.

An example of a prior art process for crushing a polyurethane foam, described in British Patent Specification No. 1,065,004 product described in British Patent Specification No. 1,253,845, which product comprises a substrate of one or more sheets of compressed cellular plastic material, the substrate having one face relatively more highly compressed than the other face, the less highly compressed face being provided with an adhesive. The less highly compressed face of that dressing is therefore intended for con-

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ERRATUM

SPECIFICATION NO 1450201

Page 1, Heading, (61) Patent of Addition to No *delete* 1419962 *insert* 1417962

THE PATENT OFFICE
13 October 1976

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SPECIFICATION NO 1450201
SLIP NO. 2
Inventor: PETER MAURICE LOCK

By a further direction given under Section 17 (1) of the Patents Act 1949 this application proceeded in the name of MONTEDISON PHARMACEUTICALS LIMITED, a British Company, of Kingmaker House, Barnet, Herts.

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SEE ERRATA SLIP ATTACHED.

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(54) ABSORBENT POLYURETHANE FOAMS AND THEIR APPLICATION AS SURGICAL DRESSINGS

(71) I, PETER MAURICE LOCK, a British Subject, of "Petrosa", 53B Maidstone Road, Rainham, Gillingham, Kent, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to absorbent polyurethane foam materials. Such materials have particular application as surgical dressings.

Dressing materials designed for wounds must have several properties; one is that a dressing should be absorbant to remove exudate from the wound and at the same time be capable of protecting the wound from injury as well as reducing the risk of infection thereof by harmful bacteria. Furthermore, wound dressing materials must be free of toxic substances which may be absorbed into the wound.

Known dressings, such as cotton lint, cotton wool pads or cotton/rayon wool pads faced with non-woven materials, have good absorbant qualities, but their surface fibres tend to adhere to the wound or to absorb the scab-forming serum so that they actually become embedded in the scab as it coagulates and hardens. Thus, if these dressings are removed to allow inspection and treatment of the wound, the wound tissue and/or the scab may be damaged thus retarding the healing process of the body or even re-opening the wound.

Attempts have been made to provide wound dressings of fully occlusive materials such as polythene and while such dressings provide a satisfactory skin regeneration environment in the vicinity of the wound, it is essential to apply them to a wound in a sterile state under sterile conditions to prevent harmful bacteria breeding close to or in the wound; this material does not absorb exudate satisfactorily, thus causing pooling in the wound which is not desirable.

Processes for subjection of polyurethane foams to heat and pressure are well known in the prior art. It is to be understood that the present invention does not claim as novel such processes in general, but rather provides a disclosure enabling certain polyurethane foams to be rendered absorbent by application of a heat/pressure treatment.

An example of a prior art process for crushing a polyurethane foam, described in British Patent Specification No. 1,065,994, is one which comprises crushing the dry body of a polyurethane foam irreversibly at an elevated temperature, preferably between 300°F and 400°F and preferably under a pressure of 4 tons per square inch.

Such a process is not confined to foam cells adjacent a surface of the foam; one requirement which is specified is the necessity to heat the entire thickness of the foam to the required temperature range so as to obtain a predominate amount of crushed cells unlike the present invention in which heat may be applied directly to one surface. Furthermore, the product from the said process is intended for lamination to a textile material, for example, a woven or knitted material to provide a dimensional stabiliser while adding crease resistance and thermal insulation. The said specification makes no reference to the foam having any absorbent properties which is in accordance with the fact that such an application would require that the crushed foam product should not have lyophilic or absorbent characteristics. The above two factors distinguish the nature and function of the crushed foam of Patent No. 1,065,994 from the present applicant's invention.

The prior art also provides examples of compressed polyurethane foams used for surgical dressings. One such example is the product described in British Patent Specification No. 1,253,845, which product comprises a substrate of one or more sheets of compressed cellular plastic material, the substrate having one face relatively more highly compressed than the other face, the less highly compressed face being provided with an adhesive. The less highly compressed face of that dressing is therefore intended for con-

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tact with the wound and the more highly compressed face is said to be substantially impermeable to water. Thus the compression taught by the above Patent has the effect of rendering the treated surface non-absorbent and is in contrast to the process of the present invention which renders the treated surface absorbent.

According to the present invention there is provided a reticulated polyurethane foam material the foam cells adjacent at least one surface of which are irreversibly partially collapsed relative to foam cells remote from said surface, and which surface is absorbent to aqueous based liquids.

The foam cells adjacent said absorbent surface have been defined as "irreversibly partially collapsed". It is known that polyurethane foam can be reversibly deformed or compressed to reduce the thickness up to a certain extent, but will substantially recover its original thickness upon washing or steam heating. The present invention relates to compression of the surface of the foam beyond this predetermined extent, that is to an "irreversible" process. The cells defined as "partially collapsed" have their wall members deformed to produce smaller cells, but it is important that the cells are not completely collapsed or fused. Such an effect is produced by controlling the heat/pressure/temperature parameters employed.

Experiments have shown that certain reticulated foams can be rendered absorbent by appropriate selection of the heat/pressure/temperature parameters.

By the term "reticulated foam" is meant a foam consisting of numerous individual cells which are constructed of a three-dimensional skeletal structure formed by the intersecting cell wall members and of interconnected strands with most or all of the membranes or windows partitioning adjacent cells being absent, such that substantially only the skeletal structure is present.

The foam article of the present invention is preferably in the form of a sheet, strip or ribbon and both of the major surfaces thereof may be of increased density; where both surfaces of the foam are of increased density, the densities of the two surfaces may be the same or different.

According to a further aspect of the present invention, there is provided a process for making a reticulated polyurethane foam material which comprises applying pressure and heat to a surface of a piece of hydrophobic polyurethane foam to irreversibly partially collapse the foam cells adjacent said surface to an extent such that said surface is rendered absorbent to aqueous based liquids. Said heat and pressure may be applied to said surface by means of a heated plate or roller or the surface may be subjected to a pressure step following a heat applying step. The heating step may be carried out using any suitable heating means such as infra-red radiation or microwaves.

The surface of the foam which is to be treated is heated to a temperature not less than the softening point of the foam but less than the fusion temperature of the foam. This varies for different foams and the surface temperature of the foam may suitably be from 200°C to 300°C depending on the time it is subjected to the heat. Preferably the applied temperature is just below the fusion temperature of the foam and is desirably from 200°C to 270°C.

The applied pressure may for example be from almost 0 up 200 lbs/sq. in. and is preferably from 5 to 100 lbs/sq. in.

During the combined pressure and heat treatment a sheet of release material, for example paper treated with silicones, may be placed between the heating means and the surface of the foam to prevent adhesion of the foam material to the plate or roller. In a treatment in which pressure is applied after the foam has been heated the release material may be employed only for the pressure application.

The initial piece of foam may be of any suitable thickness but is preferably from 1 cm to 10 cm in thickness and is preferably modified by heat and pressure to a final thickness of from 0.5 cm to 5 cm, preferably with a compressed absorbent surface thickness of up to 5 mm. To obtain the desired absorbent result, the foam material is usually reduced to about half, e.g. from 40% to 60% of its original thickness. However, this is not essential; very thin pieces of foam material approximately 3 mm thickness can be made absorbent by this process and it is only necessary to modify the surface to a depth of say 0.4 mm to achieve a satisfactory result.

The foam sheet, strip or ribbon may be similarly modified on both faces for which purpose the foam after being removed from between the plate or roller and the release coated paper (if present) is reversed and the operation is repeated. Alternatively the pressure plate may be heated to a foam modifying temperature so that both surfaces of the foam or even the full thickness of the foam may be modified by heat and pressure in one or more pressing and heating operations.

The foam articles of the present invention are particularly advantageous for use as surgical dressing materials. In this respect, the product can be readily sterilised, for example, by means of a steam autoclave, gamma radiation or ethylene oxide. Also the body of the dressing material is suitable for incorporating a medicament, such as an antibacterial and/or antiseptic. The dressing is impregnated with such a medicament after the heat/pressure/treatment but prior to any

sterilisation process. The dressing may be treated by depositing a film of medicated material on to the dressing or by dipping the dressing into a solution of medication material and then drying the material.

The foam which is employed in the invention may be a polyurethane foam based on a polyester or a polyether. However, not all foams within this definition produce the desired absorbent result. The applicant has attempted to determine a physical or chemical characteristic which may predict that a particular polyurethane foam will be rendered absorbent. It is thought that the presence in the foam of stannous octoate and trichlorofluoromethane is important although the invention is not limited to this feature. In general it is necessary to test each given sample of foam, but two preferred formulations of foam are set out below. The density cell size and weight of the initial foam material may be chosen for the particular application for which the absorbent product is required.

It has been found that all samples of foams which have been tested do not produce an absorbent result. It is likely that the shape and structure of the cells in the foam are important. The heat and pressure treatment of the foam has the effect of causing the foam cells to coalesce to give the surface region of the foam the quality of being sufficiently occlusive to engender body healing processes and yet being sufficiently absorptive that it can absorb serum exuding from the wound.

From a further aspect the present invention provides a method of treating wounds in non-human mammals which method comprises applying to the wound a surgical dressing of the present invention.

Amongst possible applications of the surgical dressing material of the present invention, there may be mentioned simple wound-dressings, post-operative wound dressings, adhesive plaster dressings, and swabs for general and medical use.

It is envisaged that, for application as an adhesive plaster dressing, the material would be produced with a thin plastics film laminated to one side thereof and on the other side of the material an adhesive layer protected by a strippable sheet.

Swabs made from the material may be rendered radio-opaque by impregnation thereof by a radio-opaque agent such as, barium sulphate or iodine extractive or by any other suitable technique.

Preferably the foam is manufactured from a formulation comprising one of the following compositions by weight:

	Parts by weight	Parts by weight
polyoxypropylene glycol	100	100
stannous octoate	0.2—3.0	0.1—1.0
water	1—10	1—10
dimethylethanolamine	0.1—1.0	0.1—1.0
silicone oil	1—10	1—10
trichlorofluoromethane	10—20	10—20
toluene-di-isocyanate	70—90	25—50

Further applications for the material of the present invention exist, such as, foam bandages to replace crepe and conforming bandages, foam eye pads to replace conventional gauze and wool pads, foam adhesive sheets to replace felt and other orthopaedic paddings, foam pressure-relief pads, foam dressing packs for use in the treatment of varicose veins by the injection technique, impregnated dressings, foam positioning sets, foam face masks and foam preparation swabs.

The material also has applications in many fields other than medicine. It has been found, for example, that material according to the present invention is excellent for the removal of condensation from windows or the like or for mopping up moisture from articles such as crockery, glassware, cars and floors.

A further envisaged use for the material according to this invention is as a lightweight body-insulative material capable of absorbing large quantities of perspiration.

A dressing prepared according to the invention has numerous advantages and desirable features, amongst which may be mentioned the following:

a) The dressing speeds up the healing process.

b) The dressing is very soft and therefore causes little or no discomfort to a patient.

c) The dressing can conform to virtually any anatomical contour and, therefore, ensure an even distribution of pressure over the skin surface of a patient.

d) The resilience of the dressing enables continuous contact with a wound, contusion, swelling or the like to be maintained even in the case where swelling or oedema subsides.

e) All exudates from the injured tissue are carried into the foam from the absorbent surface thereof, thereby leaving said surface in a soft and pliant state.

f) The dressing has desirable non-adhesive properties which simplify the removal of dressings and the inspection of the skin surface.

g) The dressing is X-ray transparent and can therefore be left *in situ* while X-ray

inspection of the wound, injury or the like takes place.

h) The dressing can be used as a haemostatic dressing.

i) The ability of the dressing to accommodate generous amounts of blood and/or exudate, allows the dressing to remain on the affected site for longer than is the case with conventional dressings.

j) The dressing will not support bacterial growth.

My Patent No. 1,417,962 describes and claims a non-reticulated polyurethane foam material, the foam cells adjacent at least one surface of which are irreversibly partially collapsed relative to foam cells remote from said surface, and which surface is absorbent to aqueous-based liquids. It also describes and claims a process for rendering absorbent a surface of a non-reticulated polyurethane foam material which comprises applying heat and pressure to said surface so as to irreversibly partially collapse foam cells adjacent said surface relative to foam cells remote from said surface, the conditions of application of the pressure and heat and the particular foam being so selected that said surface is thereby rendered absorbent.

WHAT I CLAIM IS:—

1. A reticulated polyurethane foam material, the foam cells adjacent at least one surface of which are irreversibly partially collapsed relative to foam cells remote from said surface, and which surface is absorbent to aqueous based liquids.

2. A material as claimed in Claim 1, wherein the original foam is manufactured from a formulation comprising stannous octoate and trichlorofluoromethane.

3. A material as claimed in Claim 2, wherein the original foam is manufactured from a formulation comprising the following composition by weight:

	parts
Polyoxypropylene glycol	100
Stannous octoate	0.2—0.3
Water	1—10
Dimethylethanolamine	0.1—1.0
Silicone oil	1—10
Trichlorofluoromethane	10—20
Toluene di-isocyanate	70—90

4. A material as claimed in Claim 2, wherein the original foam is manufactured from a formulation comprising the following composition by weight:

	parts
Polyoxypropylene glycol	100
Stannous octoate	0.1—1.0
Water	1—10
Dimethylethanolamine	0.1—1.0
Silicone oil	1—10
Trichlorofluoromethane	10—20
Toluene di-isocyanate	25—50

5. A polyurethane foam material as claimed in Claim 1 substantially as hereinbefore particularly described.

6. A process for rendering absorbent a surface of a reticulated polyurethane foam material which comprises applying pressure and heat to said surface so as to irreversibly partially collapse foam cells adjacent said surface relative to foam cells remote from said surface, the conditions of application of the pressure and heat and the particular foam being so selected that said surface is thereby rendered absorbent.

7. A process as clamed in Claim 6, wherein said heat and pressure is applied to said surface by means of a heated plate or roller.

8. A process as claimed in Claim 6, wherein the heating step is carried out upon the foam before the pressure step is carried out thereupon.

9. A process as claimed in Claim 8, wherein said heating step is carried out by means of infrared radiation or by means of microwaves.

10. A process as claimed in any of Claims 6 to 9, wherein the said surface of the foam is heated to a temperature from 200°C to 300°C.

11. A process as claimed in Claim 10, wherein the said surface of the foam is heated to a temperature from 200°C to 270°C.

12. A process as claimed in any of Claims 6 to 11, wherein the pressure applied to the said surface is from 5 to 100 lbs/sq. in.

13. A process as claimed in any one of Claims 6 to 12, wherein the original thickness of said foam is reduced to a range of between 40% and 60% of its original thickness.

14. A process as claimed in any one of Claims 6 to 13, wherein the resulting foam is further subjected to a process of sterilisation.

15. A process as claimed in Claim 14, wherein the sterilisation is achieved by means of a steam autoclave, gamma radiation, or ethylene oxide treatment.

16. A process as claimed in any one of Claims 6 to 15, wherein a polyurethane foam based on a polyester is employed as the original foam.

17. A process as claimed in any one of Claims 6 to 15, wherein a polyurethane foam based on a polyether is employed as the original foam..

18. A process as claimed in Claim 17, wherein the original foam is manufactured from a formulation comprising stannous octoate and trichlorofluoromethane.

19. A process for rendering absorbent a surface of a polyurethane foam material as claimed in Claim 6 and substantially as hereinbefore described.

20. A polyurethane foam material having an absorbent surface, when prepared by a

process as claimed in any one of Claims 6 to 19.

21. An article having a surgical or moisture-absorbing application, which comprises a polyurethane foam material as claimed in any one of Claims 1 to 5 or 20.

22. A surgical dressing whereof a vulnerary surface is provided by a polyurethane foam material as claimed in any of Claims 1 to 5 or 20.

23. A surgical dressing as claimed in Claim 22, wherein a medicament is incorporated in the foam.

24. A surgical dressing as claimed in Claim 23, wherein said medicament is an antibacterial or antiseptic medicament.

25. A surgical dressing, as claimed in any of Claims 22 to 24, having two major surfaces which have been rendered absorbent.

26. A surgical dressing as claimed in Claim 22 and substantially as hereinbefore described.

27. An adhesive plaster dressing which incorporates as a vulnerary surface thereof a polyurethane foam material as claimed in any of Claims 1 to 5 or in Claim 20.

28. A swab which comprises a reticulated polyurethane foam material as claimed in any of Claims 1 to 5 or Claim 20.

29. A swab according to Claim 28, which constitutes a medical swab.

30. A swab according to Claim 28, which constitutes a floor swab.

31. A light-weight thermally-insulative material capable of absorbing perspiration, which comprises a reticulated polyurethane foam material as claimed in any of Claims 1 to 5 or in Claim 20.

32. A method of treating wounds in non-human mammals which method comprises applying to the wound a surgical dressing as claimed in any one of Claims 22 to 26.

GEE & CO.,
Chartered Patent Agents,
51/52 Chancery Lane,
London, WC2A 1HL,
and
39, Epsom Road,
Guildford, Surrey.
Agents for the Applicants.

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